AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application.

Listing of Claims

Claims 1-17. (Canceled)

18. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:
providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member; and
drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;
wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;
~~wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and
wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

19. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:
providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto said microprotrusions; and
drying said applied aqueous solution to form a dry agent-containing coating on said microprotrusions, said coating being less than a thickness of the microprotrusions;
wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater

than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

~~wherein the coating provides systemic delivery of a least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

20. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions; said microprotrusions adapted to pierce through the stratum corneum to a depth of less than about 500 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

~~wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

21 (Canceled).

22. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusions having a length of less than 500 micrometers and a thickness of less than 25 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

~~wherein the coating provides systemic delivery of a least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

23. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member, said pharmacologically active agent selected from the group consisting of adrenocorticotropic hormone (ACTH (1-24)), calcitonin, desmopressin, leutinizing hormone releasing hormone (LHRH), goserelin, leuprolide, buserelin, triptorelin, parathyroid hormone (PTH), vasopressin, deamino [Val4, D-Arg8] arginine vasopressin, interferon alpha, interferon beta, interferon gamma, follicle stimulating hormone (FSH), erythoropoietin (EPO), granulocyte macrophage colony stimulating factor (GM-CSF), granulocyte colony stimulating factor (G-CSF), interleukin-10 (IL-10), glucagon, and growth regulatory factor (GRF); and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

~~wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

24. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent desmopressin onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

~~wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

Claims 25-27. (Canceled)

28. (Withdrawn) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member in a pattern; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

29. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratus corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

~~wherein the coating provides systemic delivery of a least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

30. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;

wherein said agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 50 centipoises;

~~wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and

wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

31. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 50 micrometers;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;

~~wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and
wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

32. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:
providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member; and
drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 25 micrometers;
wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;
~~wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and
wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

33. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:
providing a member having a plurality of stratum corneum-piercing microprotrusions;
providing an aqueous solution comprising said pharmacologically active agent and an adjuvant;
applying said aqueous solution onto the member; and
drying said applied aqueous solution to form a dry agent-containing and adjuvant-containing coating on said member, said coating being less than a thickness of the microprotrusions;
wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;
~~wherein the coating provides systemic delivery of a least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and
wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

34. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:
providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member; and
drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating comprising a loading of said pharmacologically active agent of less than 1 mg/cm^2 of area of said member, and said coating being less than a thickness of the microprotrusions;
wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises;
~~wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and
wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

35. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:
providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member; and
drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating comprising a loading of said pharmacologically active agent of less than 0.5 mg/cm^2 of area of said member, and said coating being less than a thickness of the microprotrusions;
wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said agent having an aqueous solution having a viscosity at about 25°C less than about 500 centipoises;
~~wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and
wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

36-46 (Cancelled).

47. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:
providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto said member by dip coating said member in said solution; and
drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions;
wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C of less than about 500 centipoises;
~~wherein the coating provides systemic delivery of a least 25% of the agent upon application of the device to the skin of a subject for 5 seconds;~~ and
wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

48-50. (Canceled)

51. (New) The method of claim 19, wherein the coating provides systemic delivery of about 25% to 50% of the agent upon application of the device to the skin of a subject for 5 seconds.

52. (New) The method of claim 51, wherein the agent comprises desmopressin or hGH.

53. (New) The method of claim 19, wherein the coating provides delivery in the skin of at least about 80% of the agent upon application of the device to the skin of a subject for 5 seconds.